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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156

58475 7590 04/10/2007
FOLEY HOAG, LLP
PATENT GROUP (w/HUV HMV)
155 SEAPORT BLVD.
BOSTON, MA 02210-2600

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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04/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 09/575,580	Applicant(s) MCKEON ET AL.	
	Examiner Chih-Min Kam	Art Unit 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 29 March 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____
 Claim(s) objected to: 17-19, 21-23 and 27-29.
 Claim(s) rejected: 8-10, 20 and 24-26.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 17, 18, 21, 22, 27 and 28, under 35 U.S.C 112, first paragraph, written description in view of applicants' response .

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's reply does not overcome the rejection of claims 8-10, 20 and 24-26 under 35 U.S.C 112, first paragraph, written description .

Applicants indicate the specification provides extensive information regarding structure to function/activity relationship of Csp 1 (SEQ ID NO: 4) and that of a fragment of amino acids 50-197 of SEQ ID NO: 4. For example, Figure 5 shows the domains in Csp1 that are involved in calcineurin binding and inhibition (see page 127, lines 1-26). Furthermore, the specification describes that Csp.1 comprises a sequence element (ERMRRP), which is located in the C-terminal half of the protein, and which appears to be similar to the consensus autoinhibitory domain of mammalian calcineurin (page 127, lines 15-19). The specification further describes that separate mutations affecting the ERM, RRPE or other conserved sequence elements such as LIS 108, did not prevent Csp 1 's inhibition of calcineuin-dependent translocation of NF-AT to the nucleus, nor Csp1 binding to calcineurin in vitro (page 127, lines 20-22). Regarding Csp2 (SEQ ID NO: 5), the specification describes that Csp2 lacks the ERM sequence, but shares considerable homology with Csp1 in a sequence block that is highly conserved in the Csp's and contains basic residues (PKPKIIQTRPE) (page 127, lines 17-19). Thus, the specification provides extensive structure to function/activity description (pages 4-5 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. While the specification discloses two regions of C-terminal half of the Csp1 protein appears sufficient to bind calcineurin (Fig. 5; pages 125, line 25-page 127, line 26), the specification does not describe a genus of variants for functional amino acid sequences at least 90% identical to the amino acid sequence of residues 50-197 of SEQ ID NO:4, or SEQ ID NO:4 or 5 for the claimed method. A single species of residues 50-197 of SEQ ID NO:4 or the amino acid sequence of SEQ ID NO:4 or 5 does not provide sufficient description for a genus of variants for functional amino acid sequences at least 90% identical to the amino acid sequence of residues 50-197 of SEQ ID NO:4, or SEQ ID NO:4 or 5 for the claimed method. The lack of description on the functional variants of SEQ ID NO:4 or 5, and the lack of representative species for the claimed method as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention (see also paragraph 4 in the Office Action dated 9/26/06).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK
April 5, 2007